UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDE AND TOXIC SUBSTANCES

MEMORANDUM

Date: 28-January-2010

SUBJECT: **Tebuthiuron:** Response to comments from Dow Agro Sciences on the Registration Review Summary Document (Docket EPA-HQ-OPP-2009-0327).

PC Code: 105501	**DP Barcode:** D372760
MRID No.: NA	**Registration No.:** NA
Petition No.: NA	**Regulatory Action:** NA
Assessment Type: NA	**Reregistration Case No.:** 0054
TXR No.: NA	**CAS No.:** 34014-18-1

FROM: P. Yvonne Barnes, Chemist/Risk Assessor P. Yvonne Barnes
Judy Facey, Ph.D., Toxicologist Judy Facey 1/28/10
Risk Assessment Branch VI
Health Effects Division (7509P)
Office of Pesticide Programs

THROUGH: Felecia Fort, Chief Felecia Fort 1/28/10
Risk Assessment Branch VI
Health Effects Division (7509P)
Office of Pesticide Programs

TO: Wilhelmena Livingston
Special Review Branch I
Special Review Reregistration Division (7508P)
Office of Pesticide Programs

I. ACTION REQUESTED

The Health Effects Division (HED) was requested to respond to comments from Dow Agro Sciences on the Reregistration Review Scoping document for Tebuthiuron (Docket EPA-HQ-OPP-2009-0327).

II. BACKGROUND

In the scoping document, DP Barcode Number: D363983 dated 23-July-2009. HED concluded that it does not anticipate additional occupational/residential exposure data. However, the residue chemistry and toxicology data listed below will be required for the tebuthiuron registration review process:

(1) A confined field rotational crop study will be conditionally required unless the registrant can provide information that the pastureland use area is either insignificant in acreage or is predominantly perennial grasses that are not rotated annually. (S. Piper, D277103, 09-Apr-02).

(2) OPPTS Test Guideline Number: 870.7800 Immunotoxicity on Tebuthiuron.

(3) OPPTS Test Guideline Number: 870.6200 Neurotoxicity Battery for Tebuthiuron.

By means of the Federal eRulemaking Portal, Dow AgroSciences submitted comments to the docket EPA-HQ-OPP-2009-0327 pertaining to the Registration Review Scoping document for Tebuthiuron. These responses address the comments directly related to the HED Registration Review Scoping document. HED responds below to the comments identified as number(s) 1, 2 and 3 in the document referenced.

III. RESPONSE TO COMMENTS

(1) HED concluded that a confined field rotational crop study would be conditionally required unless the registrant can provide information that the pastureland use area is either insignificant in acreage or is predominantly perennial grasses that are not rotated annually.

Dow AgroSciences' Comment #1: *Tebuthiuron is only used for the restoration of natural grassland vegetation in rangeland, permanent pastures and in non-cropland areas such as energy and transportation rights-of-ways. Annual grasses have a low tolerance to tebuthiuron and can be significantly damaged by broadcast applications as low as 0.3 lb a.i./acre. Since tebuthiuron is a residual herbicide that expresses its activity over several years, use on annual crops is precluded.*

Agency response: The registrant indicates that most land treated with Tebuthiuron is not retreated for 10 to 15 years, if ever. Also, damage may occur to perennial grasses due to Tebuthiurons' persistent residual herbicidal activity. HED concurs that the registrant has

provided adequate information pertaining to pasturelands and perennial grasses; a rotational crop study is therefore not required. Note: In reference to the above use of the term "crops," Tebuthiuron has no agricultural uses.

(2) HED concluded that OPPTS Test Guideline Number: 870.7800 Immunotoxicity on Tebuthiuron would be required.

Dow AgroSciences' Comment #2: *Dow AgroSciences agrees to provide an Immunotoxicity study for tebuthiuron to upgrade the registration package and address this new guideline. We look forward to discussion of the timeline for the conduct and submission of this information.*

Agency response: The Agency looks forward to discussing the timeline and submission of this study.

(3) HED concluded that OPPTS Test Guideline Number: 870.6200 Neurotoxicity Battery for Tebuthiuron would be required.

Dow AgroSciences' Comment #3: *In the Tebuthiuron Registration Review Scoping Document for Human Health Assessments (US EPA, 7/23/09, Docket EPA-HQ-OPP-2009-0327), a neurotoxicity battery (acute and sub-chronic neurotoxicity) was highlighted as a data gap for the tebuthiuron registration review process. Following a comprehensive review of available toxicity data, Dow AgroSciences believes that existing studies for tebuthiuron provide an adequate degree of confidence that tebuthiuron does not present a neurotoxic hazard. In addition, upon review of the use pattern for this active ingredient, it is clear that the potential for human exposure to tebuthiuron is in fact extremely low. Given no evidence of neurotoxicity in repeat-dose studies as well as very low potential for exposure, any risk for effects on the nervous system associated with tebuthiuron use is considered to be negligible. Furthermore, it is highly unlikely that the conduct of these studies would have any impact on the toxicology end-points used for risk assessment. Based on this rationale. Dow AgroSciences respectfully requests a waiver be granted for the requirement for the acute and sub-chronic neurotoxicity studies for tebuthiuron. Granting such will also be in accord with government and industry stewardship efforts to reduce the use of animals in toxicology studies.*

Agency response: The Health Effects Division have re-evaluated the available toxicity database for the pesticide tebuthiuron to look at it's neurotoxicity potential. Evaluation of the available subchronic, chronic and reproduction toxicity studies did not reveal any treatment- related effects on the central or peripheral nervous system of mice, rats, or rabbits. No changes in clinical signs, brain weights, gross necropsy results or histopathological results suggested any part of the nervous system was affected.

In addition, both the acute and chronic population adjusted doses (PADs) are less than 1%. Even though these low exposure numbers are conservative, most land treated with tebuthiuron is not retreated for 10 or 15 years and quite often will never be retreated. No acute or chronic risk concerns were identified from exposure to tebuthiuron in drinking water. Tebuthiuron is only

used for the restoration of natural grassland vegetation in rangeland, permanent pastures and in non-cropland areas such as energy and transportation rights-of-ways.

Upon evaluation of the available studies along with the information provided by Dow AgroSciences, (use pattern in years and used on non-cropland areas), HED has decided to grant the waiver request for the required acute and subchronic neurotoxicity studies for tebuthiuron.